K132073

ST. JUDE MEDICAL

510(k) Summary	
510(k) Number	To be assigned
Submitter Information:	
Date Prepared:	July 02, 2013
Submitter Name & Address:	St. Jude Medical One St. Jude Medical Drive St. Paul, MN 55117
Contact Person:	Kris Miller Regulatory Affairs Specialist Phone (651) 756-2954 Fax (651) 756-3298 KMiller03@sjm.com SEP 0 9 2013
Device Information:	
Trade Name:	WorkMate Claris System
Common Name:	Programmable Diagnostic Computer
Class	II
Classification Name:	870.1425, computer, diagnostic, programmable DQK
Predicate Device:	EP-WorkMate System (K092810)
	EP-NurseMate and EP-NurseMate with Physio Module (K093583)
Device Description: WorkMate Claris System	The WorkMate Claris System is a computer-based electrophysiological recording and monitoring system that is used to capture, display, store, and retrieve surface and intracardiac electrical signals during electrophysiology studies. It consists of a computer, two 23" high-resolution monitors, a multi-channel signal amplifier and filtering system (signal conditioning unit), one or two catheter input modules (CIMs), a printer, and carts. The system may also be configured with an integrated EP-4™ Cardiac Stimulator and touch-screen computer monitor (cleared in K092913). The WorkMate Claris System is connected to electrophysiology catheters that are guided into various locations within the heart, and to surface electrocardiogram (ECG) cables. Intracardiac and ECG signals are then acquired from electrodes on the indwelling catheters and ECG leads connected to the amplifier, which amplifies and conditions the signals before they are received by the WorkMate Claris System computer for display, measurement and storage. During the procedure, cardiac signals are acquired and an automated software

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	waveform detector (trigger) performs online recognition of cardiac activation on preselected leads. Temporal interval measurements are computed on multiple channels on a beat-by-beat basis and dynamically displayed on the real-time display. Menu-driven software is utilized for data acquisition and analysis, interval posting, and instant data retrieval with waveform markers and intervals displayed. Signals are also presented on a review monitor for measurement and analysis. Continuous capture of the digitized signals can be invoked, and the user can also retrieve and display earlier passages of the current study without interruption of the realtime display. The system can also acquire, display and record data from other interfaced devices in use during the procedure, such as imaging devices and ablation generators.
Device Description: WorkMate Scribe Module	The WorkMate Scribe Module consists of a PC, a touch screen LCD monitor and cart connected via Ethernet to a WorkMate Claris System. Vital signs measurements can be imported from an optional external Physiological Module (Smiths Medical Advisor™ Vital Signs Monitor herein referred to as Physio Monitor). Patient data stored on the WorkMate Claris System can be reviewed, measured and annotated. Real Time signals currently being acquired by the WorkMate Claris System can be viewed. The product is an add-on extension of the WorkMate Claris System that allows a second user to view and annotate a study in parallel with the System user.
Indications for Use	The WorkMate Claris System is indicated for use during clinical electrophysiology procedures.
Predicate Indications for Use	The EP-WorkMate System is indicated for use during clinical electrophysiology procedures. The EP-NurseMate is indicated for use during clinical electrophysiology procedures.
Comparison to Predicate Devices	The WorkMate Claris System which includes the WorkMate Scribe Module has the same intended use and fundamental scientific technology as the predicate devices. The technological characteristics of the WorkMate Claris System are substantially equivalent to the predicate devices including packaging and labeling. Through bench testing, it was demonstrated that the design modifications do not adversely affect the safety and effectiveness.
Summary on Non-Clinical Testing	The WorkMate Claris System has been designed and tested to applicable safety standards and St. Jude Medical SOPs, including design controls and risk analysis. Design verification activities for mechanical and functional testing were performed with their respective acceptance criteria to ensure that the hardware and limited software modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications.

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Statement of Equivalence	The WorkMate Claris System which includes the WorkMate Scribe Module has the same indications for use as the predicate devices. The trade names have been changed The technological characteristics for the devices are the same as the predicate devices. Based on this and the data provided in this pre-market notification, the subject devices and predicate devices have been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 9, 2013

St. Jude Medical
Kris Miller
Regulatory Specialist II
One St. Jude Medical Drive
St. Paul, MN 55117 US

Re: K132073
Trade/Device Name: WorkMate Claris System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: August 21, 2013
Received: August 22, 2013

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K132073

Device Name: WorkMate™ Claris™ System

Indications for Use:

The WorkMate™ Claris™ System is indicated for use during clinical electrophysiology procedures.

Prescription Use		Over-The-Counter Use
X	AND/OR	
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.09.09 10:18:56 -04'00'